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| APPLICATION NO. FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------------|----------------|----------------------|---------------------|------------------|
| 10/698,404 11/03/2003 | | Lou Blasetti | 70869-0066C | 2868 |
| 22902 7 | 590 06/27/2005 | | EXAMINER | |
| CLARK & BRODY | | MENON, KRISHNAN S | | |
| 1090 VERMONT AVENUE, NW SUITE 250 | | | ART UNIT | PAPER NUMBER |
| WASHINGTON, DC 20005 | | | 1723 | |

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | aN . | | | | | | |
|--|---|---|--|--|--|--|--|--|
| - | | Application N | 0. | Applicant(s) | | | | |
| Office Action Summary | | 10/698,404 | | BLASETTI, LOU | | | | |
| | | Examiner | | Art Unit | | | | |
| | | Krishnan S. M | | 1723 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| THE - Exter after - If the - If NO - Failu Any r | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply repriod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, he y within the statutory vill apply and will exp , cause the applicatio | owever, may a reply be tim minimum of thirty (30) days re SIX (6) MONTHS from n to become ABANDONEI | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | · | | | | | | | |
| 1)🖂 | Responsive to communication(s) filed on 29 A | nril 2005 | | | | | | |
| | This action is FINAL . 2b) ☐ This action is non-final. | | | | | | | |
| | Since this application is in condition for allowar | | | secution as to the merits is | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Dispositi | on of Claims | . • | • | • | | | | |
| 5)□ 6)⊠ 7)□ | 7) Claim(s) is/are objected to. | | | | | | | |
| Applicati | on Papers | | | | | | | |
| 9)□ . | The specification is objected to by the Examine | r. | | | | | | |
| 10)[| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | | |
| | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| 11)□ | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| | | | is allastica Silice | Adion of 10mm 1 10-102. | | | | |
| | nder 35 U.S.C. § 119 Acknowledgment is made of a claim for foreign | priority under 3 | 35 U.S.C. § 119(a) | -(d) or (f). | | | | |
| a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| | | | • | | | | | |
| Attachment | (s) | | | | | | | |
| 1) Notice 2) Notice 3) Inform | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date | 4) [5) [6) [| Interview Summary (Paper No(s)/Mail Dat Notice of Informal Pa Other: | | | | | |

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DETAILED ACTION

Claims 1-19 are pending after the amendment of 4/29/05, of which claims 12-17 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. Claims 1-4, 6- 11 and 18-19 are rejected under 35 U.S..C. 103(a) as being unpatentable over U.S. Patent No. 5,707,331 (Wells et al) in view of U.S. Patent No. 5,589,462 (hereinafter referred to as Patat et al).

Wells et al teach a method of isolating fibrinogen concentrate comprising the steps of obtaining plasma from whole blood by centrifugation, adding fibrinogen precipitating agent including known polyethylene glycol or ammonium sulfate to plasma, recovering fibrinogen concentrate from plasma by centrifugation (see abstract; col. 1, lines 47-50; col. 2, line 44 - col. 3, line 27,' col. 5, line 15 - col. 6, line 4). Wells et al further teaches separation of fibrinogen via cryoprecipitation of plasma (see col. 6, lines 5-33). Claims 1-4, 6-11 and 18-21 essentially differs from the method of Wells et al in reciting that initial plasma is platelet rich plasma (PR.P). Patat et al teach a method of obtaining fibrinogen from cryoprecipitate derived from PRP which is obtained by

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centrifuging whole blood (see abstract; col. 4, lines 13-54). Patat et al further teach that initial product, PRP, retains numerous platelet factors including platelet derived growth factor or PDGF in cryoprecipitate and the PDGF concentration factor in the cryoprecipitate is generally greater than 10 (see col. 2, lines 47-63) and the recovered fibrinogen concentrate contains platelet factors in sufficient quantity to confer on it mitogenetic properties (see col. 3, lines 64-67). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of Wells et al to precipitate fibrinogen out of PRP instead of platelet poor plasma to obtain improved fibrinogen concentrate having PDGF to promote cicatrization as suggested by Patat et al (see col. 2, lines 21-24).

2. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wells et al in view of Patat et al as applied to claim 4 above, and further in view of U.S. Patent No. 4,985,153 (Kuroda et al).

Claim 5 essentially differs from the method of Wells et al in view of Patat et al in reciting the step of subjecting blood to a force of about 580G for about three minutes to obtain PRP. Kuroda et al teach that PR.P is obtained by centrifuging blood under gentle conditions that is at 1 100G for 5 to 6 minutes or at 300G for 15 to 20 minutes (see col. 10, lines 18-22). It would have been obvious to a person of ordinary skill in the art to modify the method of Wells et al in view of Patat et al to obtain PRP by modifying the centrifugation force and processing time to obtain PRP as suggested by Kuroda et al.

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Response to Arguments

Applicant's arguments filed 4/29/05 have been fully considered but they are not persuasive.

In response to the argument "that Patat has no recognition whatsoever that the fibrinogen yield could be increased as was set forth in the Blasetti declaration. Thus, nothing in Patat would have led one of ordinary skill in the art to modify the invention of Wells to obtain the presently claimed invention.": The Patat reference was used to show PRP as the starting material instead of plasma as taught by Wells. Claims do not reflect any increased yield of fibrinogen. However, Wells in view of Patat would inherently produce such higher yield since the starting material and the process is now similar to what is claimed. There was no declaration filed by Blasetti as argued. Examiner assumes that the applicant meant "Blasetti Specification" instead of the declaration.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon Patent Examiner 5/30/05 W. L. WALKER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700